REMARKS

This is intended as a full and complete response to the Office Action dated August 16, 2005, having a shortened statutory period for response set to expire on November 16, 2005. Please reconsider the claims pending in the application for reasons discussed below.

Claims 54-82 remain pending in the application and are shown above. Claims 32-53 have been cancelled and claims 61-82 have been added by Applicant. Claims 54-60 stand rejected by the Examiner. Reconsideration of the rejected claims is requested for reasons presented below.

Double Patenting

Claims 54 and 60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 29 of copending Application No. 10/514,895, Pub. No. U.S. 2005/0170000 A1 to *Walker et al.* (hereinafter *Walker*). Applicant respectfully traverses the rejection.

Regarding Applicant's claim 54, *Walker* recites in claim 29 a method for preparing a particulate coformulation by coprecipitating a solution of an active substance and an excipient by contacting the solution with an anti-solvent. *Walker* further teaches, in the description, that the anti-solvent fluid should be a nonsolvent for the target substance(s). (Paragraph [0061].) Therefore, *Walker* does not recite a method for preparing a coformulation of an active substance and an oligomeric or polymeric material, wherein, under the operating conditions used, the active substance is soluble in the anti-solvent and the oligomeric or polymeric material is not soluble in the anti-solvent, as recited in Applicant's claim 54.

Regarding Applicant's claim 60, *Walker* recites in claim 29 a method for preparing a particulate coformulation by coprecipitating a solution of an active substance and an excipient by contacting the solution with an anti-solvent. *Walker* does not recite a method for preparing a coformulation of an active substance and an oligomeric or polymeric material, in which between 90 and 100 % w/w of the active substance is present in an amorphous as opposed to crystalline form, and in which the

active substance represents at least 10 % ww of the coformulation, as recited in Applicant's claim 54.

Therefore, present claims 54 and 60 and *Walker's* claim 29 are patentably distinct from each other. Withdrawal of the rejection is respectfully requested.

Claim Objections

Claims 52 and 53 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. In response claims 52 and 53 have been cancelled by Applicant without prejudice.

Claim Rejections

Claims 54-56 and 58-60 stand rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/01221 (hereinafter *Hanna 1*). The Examiner asserts that *Hanna 1* discloses the subject matter as described in claims 54-56 and 58-60. Applicant respectfully traverses the rejection.

Hanna 1 discloses the formation of a particulate product by co-introducing a supercritical fluid and a vehicle containing at least one substance in solution or suspension into a particle formation vessel. *Hanna 1* further discloses using supercritical CO_2 for the formation of particles consisting of a pharmaceutical compound (salmeterol xinafoate) and a polymer matrix (hydroxypropylcellulose). These particles demonstrate a "disturbance" of crystallinity, and it is clear from the appended DSC/XRD data that significant amounts of the crystalline drug are still present. (See Figures 35, 36, 45, and 46.) Furthermore, *Hanna 1* is silent as to operating conditions where the active compound is soluble in the anti-solvent and the polymeric material is not soluble in the anti-solvent.

Therefore, *Hanna 1* does not teach, show, or suggest a method for preparing a coformulation of an active substance and an oligomeric or polymeric material produced by dispersing and extracting a fluid vehicle from a solution or suspension of a target substance with near critical or supercritical fluid anti-solvent, and wherein the active substance is soluble in the anti-solvent and the oligomeric or polymeric material is not soluble in the anti-solvent, as recited in claims 54-56 and 58-59.

Furthermore, *Hanna 1* does not teach, show, or suggest a method for preparing a coformulation of an active substance and an oligomeric or polymeric material produced by dispersing and extracting a fluid vehicle from a solution or suspension of a target substance with near critical or supercritical fluid anti-solvent, and in which between 90 and 100 % w/w of the active substance represents at least 10 % ww of the coformulation and is present in an amorphous as opposed to crystalline form, as recited by claim 60. Withdrawal of the rejection is respectfully requested.

Claims 54-60 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Hanna 1* in view of *Hanna, et al.* (U.S. Publication No. 2004/0071783 A1, hereinafter *Hanna 2*). The Examiner asserts that *Hanna 1* teaches a method for preparing a coformulation as explained above. The Examiner acknowledges that *Hanna 1* does not teach ketoprofen as an active agent, but relies on *Hanna 2* as teaching that it is known to use ketoprofen in a process utilizing SEDS. Applicant respectfully traverses the rejection.

The combination of *Hanna 1* and *Hanna 2* does not teach, show or suggest all the claim limitations of claims 54-60. The teachings of *Hanna 1* are discussed above. *Hanna 2* teaches a system in which ketoprofen is dissolved in supercritical CO_2. Particle formation occurs when the supercritical CO_2 solution is introduced through the inner passage of a two-passage coaxial nozzle and supercritical nitrogen is introduced through the outer passage. In *Hanna 2*, the supercritical CO_2 is the solvent, and the supercritical N_2 is the anti-solvent causing the target substance to crash out, and thus the ketoprofen is not soluble in the antisolvent. (See, e.g., [0016].) Furthermore, *Hanna 2* discloses crystalline particles as confirmed by the appended XRPD patterns.

Therefore, the combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation of an active substance which, under the operating conditions used, is soluble in the chosen anti-solvent, as recited in claims 54-59.

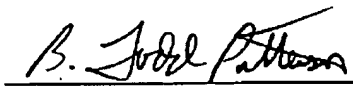
Additionally, the combination of *Hanna 1* and *Hanna 2* does not teach, show, or suggest a method for preparing a coformulation of an active substance and an oligomeric or polymeric material in which between 90 and 100 % w/w of the active substance represents at least 10 % ww of the coformulation and is present in an

amorphous as opposed to crystalline form, as recited by claim 60. Withdrawal of the rejections is respectfully requested.

In conclusion, the references cited by the Examiner, alone or in combination, do not teach, show, or suggest the claimed invention.

Having addressed all issues set out in the office action, Applicant respectfully submits that the claims are in condition for allowance and respectfully request that the claims be allowed.

Respectfully submitted,



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